



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

Docket No. CDC-2012-0002

RIN 0920-AA47

**Establishment of User Fees for Filovirus Testing of
Nonhuman Primate Liver Samples**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is amending regulations for the importation of live nonhuman primates (NHPs) by establishing a user fee for filovirus testing of all nonhuman primates that die during the HHS/CDC-required 31-day quarantine period for any reason other than trauma. We are amending the regulations to establish a filovirus testing service at HHS/CDC, because testing is no longer being offered by the only private, commercial laboratory that previously

performed these tests. This testing service will be funded through user fees.

DATES: This final rule is effective on [INSERT DATE 30 DAYS AFTER PUBLICATION TO THE FEDERAL REGISTER.]

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I. Background

On February 10, 2012, we published a notice of proposed rulemaking (NPRM) in the *Federal Register* (77 FR 7109) that provided the background, rationale, description of the services and activities covered by the user fee, an analysis of the user fee charge (cost to the government), and payment instructions. On the same date, we published a companion Direct Final Rule (DFR) (77 FR 6981). In both the NPRM and DFR, we stated that if we did not receive any significant adverse comments by April 10, 2012, we would publish a document in the *Federal Register* withdrawing the NPRM and confirming the effective date of the DFR within 30 days after the end of the comment period.

Because the DFR contained an error in effective date and HHS/CDC received a significant adverse public comment, we published a correcting amendment in the *Federal Register* on June 15, 2012 (77 FR 35878), withdrawing the DFR.

II. Public Comment Summary and Responses

HHS/CDC received four public comments on the NPRM. Three of the commenters expressed strong support for the proposal, and one commenter questioned our analysis of the rule. HHS/CDC did not receive any public comments objecting

to the amount of the user fee, which is \$540.00 USD. The comments and HHS/CDC responses are summarized below.

A. Public Comments of General Support.

One commenter indicated that the user fees would be a good idea because the testing of nonhuman primate liver samples for filovirus infection is essential for public health and safety. The commenter stated that the amount of the user fee is not exorbitant and will allow the government to continue to test NHPs. This commenter also expressed concern that the agency would be unable to continue to test NHPs absent reimbursement. Finally, the commenter indicated his/her support for the testing of animals that pose a threat to human life. A second commenter noted that it is the duty of the federal government to protect the health and welfare of its citizens from preventable dangers and that failure to do so would constitute a dereliction of duty. Further, this commenter fully supported what he/she referred to as a "reasonable fee."

HHS/CDC Response. HHS/CDC thanks the commenters for their comments.

A third commenter agreed that establishing user fees for filovirus testing of nonhuman primate liver samples was

a necessary step toward protecting public health. While this commenter offered "100%" support for the regulation, the commenter also questioned whether HHS/CDC's costs for storing records could increase the amount of the user fee in the future.

HHS/CDC Response. Although HHS/CDC has only recently begun to offer this testing service, it has collected and maintained filovirus test results from importers since the beginning of the testing requirement and expects to continue do so in the future. Because maintaining test results are an expense that HHS/CDC had already assumed, these costs were not included in the calculations of the user fee. HHS/CDC does not expect to attempt to recoup these costs in the future.

B. Public Comments Regarding Analysis of the Rule.

A commenter stated that CDC did not provide an analysis of the filovirus testing market, including the nature and extent of current and future demand for filovirus testing. The commenter requested that HHS/CDC consider and address the long-term prospects of the filovirus testing market. Specifically, the commenter stated that if the market is minimal, it would be appropriate for the government to administer and perform

the testing. On the other hand, if the market was much larger, then it may be in the interest of the public and the government to incentivize the construction of private laboratory facilities for the purpose of filovirus testing, thereby allowing the commercial market to serve the need of importers.

HHS/CDC Response. HHS/CDC disagrees with this comment. While not labeled specifically as a market analysis in the NPRM, the components of a market analysis were included in the preamble of the NPRM. Demand and market size, as calculated by revenues and numbers of requests for filovirus tests, were included in section III "Rationale for Proposal" of the NPRM and were based on the observed demand noted by, and fees charged by, the commercial laboratory that performed this service since 1990.

In section VI "Analysis of User Fee Charge (Cost to the Government)" of the NPRM, HHS/CDC noted that during the past five years, our records indicated that there were approximately 100-150 requests per year, generating revenues of \$50,000 to \$75,000 a year.

The issue of future demand was also implicitly addressed in the NPRM, where we noted that the demand for testing is driven by government requirements and the population of imported NHPs that drive the demand is

limited by regulation to scientific, exhibition or educational purposes. Thus, we do not expect that market size and demand will change substantially in the long run.

Regarding the commenter's query about the size of the market, we note that regardless of whether the filovirus testing market is measured by requests (100-150) or revenues (\$50,000 to \$75,000 a year), it is, and will continue to be, a small market from a laboratory perspective. The market revenue generated by testing is too small to create demand specifically for a "filovirus testing facility" because laboratories, especially the Biosafety Level 4 (BSL-4) laboratories needed for this type of testing, require large amounts of sunk capital. In this context, "sunk capital" is intended to mean investments in laboratory-specific equipment and facilities that cannot be resold for other businesses or used for other purposes. As explained in the NPRM, the testing procedure requires a BSL-4 laboratory for specimen processing, reagent preparation, and the testing procedure. The forecast revenues from filovirus testing of \$50,000 to \$75,000 a year would only be a fraction of the budget needed to sustain a BSL-4 type of facility needed to test for filoviruses.

We note that the estimates in the NPRM of a per-test cost of \$540.00 USD do not take into account the perspective of a commercial laboratory that would trade the costs and benefits of devoting laboratory space and resources to filovirus testing for other revenue-generating tests and services they could offer. Finally, we note that no commercial entities have entered the market of antigen-capture filovirus testing since the original commercial laboratory stopped providing this service.

Viewed as a whole, these factors (sunk capital required to perform such testing, limited market demand, and current lack of a commercial laboratory offering this service), were instrumental in shaping our view that there is likely no commercial laboratory that will enter this market in the immediate future. However, as indicated in the NPRM, nothing in this final rule prohibits a commercial laboratory from entering the market in the future.

Next, the commenter raised a series of questions regarding long run actions that CDC can take to make filovirus testing viable commercially. Specifically, the commenter said, "it may be more appropriate to examine the data and other indicators to ensure that the agency is not overlooking any externalities."

HHS/CDC Response. As noted in the NPRM, there are no private laboratories engaged in filovirus testing at this time. If HHS/CDC were to provide the tests free-of-charge, this would be a long-term disincentive for any commercial lab to enter the business because no commercial lab could compete with no-fee testing. By implementing a fee, CDC is eliminating the nature of unfair government competition created by a price that may be below standard commercial market fees, or free. The fee HHS/CDC intends to charge is consistent with the fee previously charged by the one commercial laboratory performing this type of testing. Furthermore, as HHS/CDC stated in the NPRM and above, the action taken in this rulemaking is not intended to prohibit a private sector facility from developing the capability and offering this same service in the future. When considered together, the fee, the extensive investments needed to build and maintain BSL-4 type laboratories, and the small size of the filovirus testing market, indicate that CDC can take no other short-term or long-term actions to encourage a private market for filovirus testing.

III. Alternatives Considered

As stated earlier in the Preamble, HHS/CDC believes this testing is essential to protect public health and

safety. If this testing is not provided, it will have a disruptive impact on imports of NHPs for science, educational, and exhibition purposes, that would remain in quarantine absent a negative test result.

When HHS/CDC learned that the sole commercial laboratory performing this testing was no longer offering the testing, we considered several alternatives to meet the testing requirement. One alternative was to wait for another commercial laboratory to begin performing the testing. However, as stated previously in the Preamble, another laboratory has not entered the market since the previous laboratory stopped performing this testing. Indeed, to date, no laboratory has begun offering this service in response to the NPRM.

Another alternative that HHS/CDC considered was to perform the testing in HHS/CDC laboratories at no cost. However, as commenters have noted, the cost burden of performing the testing without compensation may prevent the Agency from performing the testing indefinitely. Further, as we stated previously in the Preamble, should HHS/CDC offer this testing at no charge, it would create a disincentive to the private sector to enter the market.

Finally, HHS/CDC considered offering a filovirus testing service and establishing a user fee to cover the

cost of the testing. This is the alternative that HHS/CDC chose.

IV. Payment Instructions

As of the effective date of this rule, importers should submit a check or money order in the amount of \$540.00 USD made payable to Centers for Disease Control and Prevention for each test conducted at the time that specimens are submitted to the CDC for testing. The check(s) should be sent to Centers for Disease Control and Prevention, P.O. Box 15580, Atlanta, GA 30333.

V. Regulatory Analyses

A. Required Regulatory Analyses under Executive Orders 12866 and 13563

We have examined the impacts of the final rule under Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). Because the purpose of this rule is to provide a framework to determine a fair fee to charge for a service

that has become unavailable in private, commercial markets within the United States, we have determined that the rule will not violate the intent of either of the Executive Orders because it will in no way prevent a private entity from entering the field and providing a similar, privatized service. If any private entity expresses an interest in providing this service, we strongly encourage them to do so.

This rule is being treated as "not significant" under EO 12866. We are amending 42 CFR 71.53 to establish a filovirus testing service at HHS/CDC, because testing is no longer being offered by the only private, commercial laboratory that previously performed these tests. Thus, the rule has not been reviewed by the Office of Management and Budget (OMB).

B. Regulatory Flexibility Act

We have examined the impacts of the final rule under the Regulatory Flexibility Act (5 U.S.C. 601-612). Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze

regulatory options that would minimize any significant economic impact of a rule on small entities. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

C. Small Business Regulatory Enforcement Fairness Act of 1996

This regulatory action is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This final rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. The Paperwork Reduction Act of 1995

HHS/CDC has reviewed the information collection requirements of the final rule and has determined that the information collection requested in the final rule is already approved by the Office of Management and Budget (OMB) under OMB Control No. 0920-0263, expiration date June

30, 2014. The final rule does not contain any new data collection or record keeping requirements.

E. National Environmental Policy Act (NEPA)

Pursuant to 48 FR 9374 (list of HHS/CDC program actions that are categorically excluded from the NEPA environmental review process), HHS/CDC has determined that this action does not qualify for a categorical exclusion. In the absence of an applicable categorical exclusion, the Director, CDC, has determined that provisions amending 42 CFR 71.53 will not have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

F. Civil Justice Reform (Executive Order 12988)

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this final rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

G. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding Federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Plain Language Act of 2010

Under Public Law 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines and requested comment from the public on this topic. HHS/CDC did not receive any public comment to this request.

List of Subjects in 42 CFR Part 71

Communicable diseases, Public health, Quarantine, Reporting and recordkeeping requirements, User fees, Testing.

For the reasons discussed in the preamble, the Centers for Disease Control and Prevention amends 42 CFR part 71 as follows:

PART 71-FOREIGN QUARANTINE

■ 1. The authority citation for 42 CFR part 71 continues to read as follows:

Authority: Sec. 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 243), secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272).

Subpart F--Importations

■ 2. In § 71.53, add paragraph (j) to read as follows:

§ 71.53 Nonhuman primates.

* * * * *

(j) Filovirus testing fee. (1) Non-human primate importers shall be charged a fee for filovirus testing of non-human primate liver samples submitted to the Centers for Disease Control and Prevention (CDC).

(2) The fee shall be based on the cost of reagents and other materials necessary to perform the testing; the use of the laboratory testing facility; irradiation for inactivation of the sample; personnel costs associated with performance of the laboratory tests; and administrative

costs for test planning, review of assay results, and dissemination of test results.

(3) An up-to-date fee schedule is available from the Division of Global Migration & Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333. Any changes in the fee schedule will be published in the *Federal Register*.

(4) The fee must be paid in U.S. Dollars at the time that the importer submits the specimens to HHS/CDC for testing.

Dated: February 4, 2013.

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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